UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,298	10/16/2003	John T. Kilcoyne	1065-012US04	7921

28863 7590 07/24/2007

SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER	
NASSER, ROBERT L	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
07/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,298	KILCOYNE ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-49,55 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-49, 55, 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-34, 37-40, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al 6585644 in view of Smith 5108889. Lebel shows a device with a casing 6 adapted to be implanted and secured within a patient's body in an area where the environment has a parameter, pH, indicative of reflux, a pH sensor in the casing (see column 9, lines 40 and 41), transmitter 76 in the casing, adapted to send a glucose signal to an external receiver, a power source 74 in the casing, and a processor in the casing that supplies power to the transmitter only during certain times to minimize power consumption (see discussion of listening periods throughout). It does not supply power periodically to the sensor. However, Smith teaches that in order to further minimize power consumption, the sensor may only be energized for small periods of time (see column 50, lines 38-45). Hence, it would have been obvious to modify Lebel to periodically enable the sensor, to further conserve power. It is clear that in order for the transmitter to transmit sensed data, the sensor must be energized prior to the transmitter being energized. Claim 37 is rejected in that the transmitter is fro and transmits a digital signal. Claims 38 and 40 are rejected in that the exact time each of the transmitter and sensor are energized would have been a mere matter of design choice for one skilled in the art. Claim 39 is rejected in that the combination would have

a sensing period and a transmitting period, where only the sensor or transmitter are enabled. Claim 55 is rejected in that the casing can be immobilized in the esophagus.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al in view of Smith as applied to claims 33, 34, 37-40, and 55 above, and further in view of Cozette 5063081. Cozette teaches that a ISFET/amplifier is a known pH sensor. Hence, it would have been obvious to modify the above combination to use such a sensing system, as it is merely the substitution of one known sensor for another.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al in view of Smith as applied to claims 33, 34, 37-40, and 55 above, and further in view of Miller 4748562. Miller teaches that a antimony electrode/amplifier is a known pH sensor. Hence, it would have been obvious to modify the above combination to use such a sensing system, as it is merely the substitution of one known sensor for another.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al in view of Smith as applied to claims 33, 34, 37-40, and 55 above, and further in view of Schulman et al 6068088. Schulman further teaches providing calibrated data to an external monitor from an implanted device, where the implanted device includes a processor (in unit 16) to calibrate the data teaches storing calibration data with a sensor to ensure proper calibration of the device. The examiner notes that Schulman teaches the controller may be implanted and may be used to calibrate the data (see column 7, last paragraph) Hence, it would have been obvious to modify the combination to use a processor to calibrate the data prior to transmission out of the body, as it is merely the substitution of one known processing technique for another.

provide such calibration data from a processor such a memory, to ensure accurate measurements.

Claims 43, 45-49 are rejected under Petty 4503859 in view of Lebel et al and Smith. Petty shows an implantable pH sensor for measuring pH having a telemetry link to a data receiver (see column 4, line 5). Lebel and Smith teach respectively, that to conserve power, the transmitter and sensor should only be activated for a portion of the cycle. Hence, it would have been obvious to modify Petty to use such a power scheme, to conserve energy. Claims 45, 48, and 49 are rejected in that the exact time each of the transmitter and sensor are energized would have been a mere matter of design choice for one skilled in the art. Claim 47 is rejected in that the examiner takes official notice that rf is a well known telemetry medium.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petty in view of Lebel et al and Smith as applied to claims 43 and 45-49 above, and further in view of Cozette 5063081. Cozette teaches that a ISFET/amplifier is a known pH sensor. Hence, it would have been obvious to modify the above combination to use such a sensing system, as it is merely the substitution of one known sensor for another.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petty in view of Lebel et al and as applied to claims 43 and 45-49 above, and further in view of Miller 4748562. Miller teaches that a antimony electrode/amplifier is a known pH sensor. Hence, it would have been obvious to modify the above combination to use such a sensing system, as it is merely the substitution of one known sensor for another.

Applicant's arguments filed 4/30/2007 have been fully considered but they are not persuasive.

Applicant has asserted that Lebel does not have a casing adapted to be implanted and secured within the body at a location wherein the surrounding environment provides a parameter indicative of reflux. The examiner disagrees. In response, the examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the current case, Lebel is capable of being implanted in an environment to measure pH which would be indicative of reflux, i.e. the esophagus. The fact that Lebel does not measure parameters indicative of reflux does not mean that it is not adapted to do so.

Applicant has further asserted that the Lebel/Smith combination does not teach the relationship between the delivery of power to the sensor and the transmitter. The examiner notes that it is clear that the sensor must sense the data prior to the transmitter being able to send it. As such, it is clear that power is provided to the sensor in a first interval and to the transmitter at a second, later interval.

With respect to claims 38 and 40, applicant has stated that the examiner has provided no evidence that the time periods at issue are known or provided any motivation. The examiner notes that in the absence of a showing of unexpected results, the time periods at issue are merely obvious design modifications and are well within the realm of routine experimentation for one skilled in the art. To be more specific, the

art teaches the same concept as applicant does, with out the specifics. It is the examiner's position that it would have been well within the ability of one skilled in the art, and hence obvious, to fine tune the invention or the above combination.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser
Primary Examiner
Art Unit 3735

RLN
July 13, 2007

/Robert l. Nasser Jr./